Amendments to the Drawings:

The attached sheet of drawings includes changes to Fig. 6. This sheet, which includes Figs. 1 and 6, replaces the original sheet including Fig.1 and 6.

Attachment: Replacement Sheet

REMARKS/ARGUMENTS

Amendments to Claims Generally

Claims 2, 18, and 19 have been canceled.

Claims 1, 3 through 17, and 20 have been amended as described below in response to the Examiner's objections.

New Claims

Claims 21 through 23 have been added. Claim 21 is supported by the specification at page 9, lines 22–29. Claim 22 is supported by the specification at page 8, lines 29–33 through page 9, lines 1–6 and page 11, lines 1–11. Claim 23 is supported by the specification at page 10, lines 24–28. These claims add no new matter and should be found to be allowable by the Examiner.

Examiners Objections

1. Drawings Objections

The Examiner objected to the drawings because the second component in Figure 6 was erroneously labeled 5 instead of 2. Figure 6 has been amended to correctly label the second component as 5, not 2.

The Examiner also objected to the drawings under 37 C.F.R. § 1.83(a), stating that the magnetic sensor or detector as detailed in paragraph 2 on page 8, as well as in the claims, must be shown or the feature canceled from the claims and noting that the reference character 18 appears in the specification but not in the figures. Figure 6 has been amended to show the magnetic sensor or detector, which is labeled 18. This amendment adds no new matter and is supported by the sections of the specification that discuss that "[w]here the magnetic array is located within the lower component the magnetic sensor or detector will be located in the upper component and vice versa." (Application, page 8). In the embodiment shown in figure 6, the magnetic array [11] is located in the lower component; therefore, as per the specification description, the magnetic senor or detector is located in the upper component, as shown in the amended figure 6. The drawings, in light of the amendment to figure 6, comply with 37 C.F.R. § 1.83(a).

2. Specification Objections

The Examiner objected to the specification for the first reason that the disclosure was not in the preferred format, i.e., because an Abstract of the Disclosure was not included. The specification has now been amended to include an abstract, which is intended to commence on a separate sheet following the claims section.

The Examiner objected to the specification for the second reason that the specification contained a few typographical errors. The specification has been amended to replace the paragraphs containing those typos with paragraphs that do not include the typographical errors.

3. Claim Objections

The Examiner objected to claims 1, 2, 4, 16, 17, 18, and 19 because of several informalities. First, the Examiner stated that "[t]he medical bag was not claimed in claim 1, or any of the depending claims . . . ." The references to a "medical bag" in the claims have been amended to references to a "catheter bag." Second, the Examiner stated that, in claim 3, the term "tubulars" was unclear and was therefore interpreted as "tubular sections." Claim 3, as amended, now makes reference to "tubular sections" rather than "tubulars." Third, the Examiner stated that claim 9 was improperly dependent on claim 12 so it was assumed that claim 9 is dependent from claim 1. Claim 9, as amended, is dependent on claim 1, not 12. Fourth, the Examiner stated that claims 18 and 19 contained informalities. Claims 18 and 19 have been canceled. Fifth, the Examiner stated that claims 14, 16, and 17 refer to "the magnetic detector and the magnetic array" and depend from claim 1, but no magnetic detector or array was mentioned in claim 1, so it was assumed that the claims depend from claim 12. Claims 14, 16, and 17 have been amended to depend from claim 12.

Claim Rejections - 35 U.S.C. § 112

The Examiner has rejected claims 12 through 14 and 16 through 19 under 35 U.S.C. § 112, first paragraph, for the reason that "[t]he magnetic sensor or detector described in the claims is not shown in the figures or adequately described in the disclosure to enable one of ordinary skill in the art to which it pertains to make or use the device without undue experimentation."

Claims 18 and 19 have been canceled.

The specification explains that the "magnetic sensor or detector . . . may take the form of one or more read switches (otherwise known as reed switches)" and notes that "[w]here the magnetic array is located within the lower component the magnetic sensor or detector will be located in the upper component and vice versa." (Application, page. 8). Given this description,

and figure 6 as amended, Applicant does not believe that one of ordinary skill in the art to which it pertains would have any problem constructing a device using a reed switch and appropriate magnet in view of such systems being so well known in the art. One only has to carry out a Google search to see how well known such switches are. It is quite clear that a reed switch could be located within the upper component such that upon downward movement of the upper component due to filling of the catheter bag, the reed switch will be brought into close proximity with a magnet in the lower component, which results in completing an electric circuit, thereby activating the signaling means. There is nothing whatsoever complicated in such a system. Accordingly, claims 12 through 14 and 16 through 17 are enabled by the specification and the drawings, particularly in light of the amendment to figure 6.

Claim Rejections – 35 U.S.C. § 102

"An applicant for a patent is entitled to the patent unless the application fails to meet the requirements established by law. It is the Commissioner's duty (acting through the examining officials) to determine that all requirements of the Patent Act are met. The burden is on the Commissioner to establish that the applicant is not entitled under the law to a patent . . . . In rejecting an application, factual determinations by the PTO must be based on a preponderance of the evidence, and legal conclusions must be correct." *In re Oetiker,* 977 F.2d 1443, 1449, 24 USPQ2d 1443, 1447, 24 USPQ2d at 1447 (Fed. Cir. 1992) (Plager, J., concurring). Further, "[t]he precise language of 35 USC 102 that 'a person shall be entitled to a patent unless,' concerning novelty and unobviousness, clearly places a burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103." *In re Warner,* 379 F.2d 1011, 1016, 154 USPQ 173 (CCPA 1967), *cert. denied*, 389 U.S. 1057, *reh'g denied*, 390 U.S. 1000 (1968).

1. Gordon

The Examiner rejected claims 1, 2, 4, and 20 under 35 U.S.C. § 102(b) as being anticipated by the controlled infusion system described in United States Patent No. 3,425,415 (the Gordon patent).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 828 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). MPEP § 2131.

Claim 2 has been canceled, and claim 1 has been amended to specify that the apparatus is capable of indicating when the contents of a *catheter bag* reaches a certain level. Claims 4 and 20 depend from claim 1; therefore, they include the catheter bag limitation.

Gorden is concerned with an infusion system and therefore the emptying of a drip bag. In view of the amendments carried out to claim 1 in relation to limiting to a catheter bag, Applicant's invention is a device that is intended to indicate the *filling* of a catheter bag. Accordingly, Gordon does not include the element of claim 1 of being used with a catheter bag. Thus, Applicant respectfully contends that Gordon does not anticipate claims 1, 4, and 20.

2. Vancaillie

The Examiner rejected claims 1 through 7, 10, 11, and 15 under 35 U.S.C. § 102(b) as being anticipated by the stand with attachment for a medical bag described in United States Patent Number 5,956,130 (the Vancaillie patent).

Again, claim 2 has been canceled, and claim 1 has been amended to specify that the apparatus is capable of indicating when the contents of a *catheter bag* reaches a certain level. Claims 3 through 7, 10, and 15 depend from claim 1; therefore, they contain the catheter bag limitation. Claim 11 depends from claim 10 and therefore likewise contains the catheter bag limitation.

Vancaillie is not concerned with the filling of catheter bags and is much more complex in nature in terms of looking to compensate fluid loss from a subject by replacement with further fluid. There is no mention in Vancaillie of the medical bag being a catheter bag as is recited by the current claims, in light of the amendments thereto. Vancaillie is particularly concerned with needing to replace fluids in subjects who are losing or experiencing blood loss. In view of the complex nature and quite different medical needs, the skilled reader would not look to such a document when wishing to develop a device designed to indicate the filling of a catheter bag. Thus, Applicant respectfully contends that Vancaillie does not anticipate claims 1, 3 through 7, 10, 11, and 15.

The Examiner also rejected claims 1, 8, and 9 under 35 U.S.C. § 102(b) as being anticipated by Vancaillie.

Claims 8 and 9 depend from claim 1. Therefore, in light of the amendments to claim 1, claims 1, 8, and 9 include the limitation of use with a catheter bag. As previously discussed, Vancaillie contains no mention of a catheter bag. Thus, Applicant respectfully contends that Vancaillie does not anticipate claims 1, 8, and 9.

Claim Rejections - 35 U.S.C. § 103

The Examiner rejected claims 12 through 14 and 16 through 19 under 35 U.S.C. § 103(a) as being unpatentable (obvious) over Vancaillie in view of the patient care system described in United States Patent Number 5,906,016 (the Ferrand patent) and in further view of www.alliedelec.com. The Examiner contends that modifying the stand with indicator means of Vancaillie to include features taught by Ferrand and www.alliedelec.com would result in the present invention, with each and every element thereof.

Section 706.02(j) of the MPEP sets forth the requirements for establishing the *prima facie* case of obviousness as follows:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on the applicant's disclosure. *In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In this case, there is no suggestion or motivation to modify Vacaillie to include features of Ferrand or www.alliedelec.com, no reasonable expectation of achieving success in doing so, and such combination would not teach or suggest all the claim limitations of claims 12 through 14, 16, and 17. (Because Claims 18 and 19 have been canceled, Applicant need not discuss their nonobviousness.)

The law regarding obviousness is clear: any modification of the prior art must be suggested or motivated by the prior art.

> "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so." [citation omitted.] Although crouched in terms of combined teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious "modification" of the prior art. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.

In re Fritch, 972 F.2d 1260, 23 USPQ2d 1780, 1783–84 (Fed. Cir. 1992) (quoting, in part, *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USQP 929, 933 (Fed. Cir. 1984)). Further, even if the prior art may be modified as suggested by the Examiner, the modification is not obvious unless the prior art suggest the *desirability* for the modification. *In re Fritch*, 23 USPQ2d 1780 (Fed. Cir. 1992) (noting that the "mere fact that prior art may be modified to reflect features of claimed invention does not make the modification, and hence, the claimed invention, obvious unless the desirability of such a modification is suggested by prior art") (citing *In re Gordon*, 733 F.2d at 902, 221 USPQ at 1127). Moreover, the motivating suggestion must also be explicit. An invention cannot be found obvious unless there is "some explicit teaching or suggestion in art to motivate one of even ordinary skill to combine such elements so as to create the same invention." *Winner Int'l Royalty Corp. v. Wang*, 48 USPQ.2d 1139, 1140 (D.C.D.C. 1998).

As previously mentioned, there is no motivation or suggestion to modify Vancaillie to include limitations in Ferrand or www.alliedelec.com. Whilst magnets/reed switches are well known in the art, their use has not been suggested in relation to devices designed to monitor the filling of a catheter bag. Vancaillie teaches the use of load cells. However, as mentioned above, Vancaillie is not concerned with the filling of catheter bags and is therefore not relevant. In view of the teaching of the use of complex load cell arrangement, one skilled in the art is aware of the sensitivity as imposed by the Vancaillie teaching and would not therefore be motivated to use a simpler magnet/reed switch or even mechanical switch as described by the present invention.

In addition, the Examiner's referral to Ferrand is not understood as Ferrand is concerned with patent beds. One skilled in the art would not look at the teaching in relation to a patient's bed and use this in a device for monitoring the filling of a catheter bad.

Accordingly, there is no suggestion or motivation to combine Vancaillie with Ferrand and www.alliedelec.com, there is no reasonable expectation of success in such combination, and the combination does not teach or suggest all the claim limitations of 12 through 14, 16, and 17, i.e., the limitation of being an apparatus capable of indicating when the contents of a catheter bag reach a certain level. For the foregoing reasons, Applicant respectfully contends that claims 12 through 14, 16, and 17 are not obvious over Vancaillie in view of Ferrand and www.alliedelec.com.

Conclusion

All such changes herein add no new matter.

If the Examiner feels it would advance the application to allowance or final rejection, the Examiner is invited to telephone the undersigned at the number given below.

Reconsideration and allowance of the application as amended is respectfully requested.

DATED this 4th day of April, 2007.

Very respectfully,

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CERTIFICATE OF MAILING

I HEREBY CERTIFY that this correspondence is being electronically deposited with the United States Patent Office via the EFS-Web on the below date as addressed to:

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